Office Action Summary	Application No.	Applicant(s)	
	08/955,373	MOURITSEN ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *88-100 and 102-112* is/are pending in the application.

5a) Of the above claim(s) *88-100,104,106-110 and 112* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *102,103,105,111* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The rejection of claims 102,103,105,111 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons elaborated in the previous Office Action is withdrawn in view of the amended claims.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 102,103,105,111 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 102 is indefinite in the recitation of “the secondary structure and tertiary structure of the self-protein is preserved to a large extent” because it is unclear what this means or encompasses. It is unclear what changes to the secondary and tertiary structure would or would not be encompassed by the aforementioned term. For example, it is unclear if this term encompasses changes at the physical/chemical level (e.g. crystal structure) or simply functional changes (e.g. still immunogenic antigen as evidenced by antibody binding by antibodies specific for unmodified antigen). If the term is interpreted as encompassing changes at the physical/chemical level, it is unclear as to what deviations from the normal crystal structure would or would not be encompassed by the term “the secondary structure and tertiary structure of the pathogenic self-protein is preserved to a large extent”. It is unclear as to what changes to the secondary structure would or would not be encompassed by the aforementioned term. For example, it is unclear if this term encompasses changes at the physical/chemical level (egg. crystal structured) or simply functional changes (egg. still immunogenic antigen as evidenced by antibody binding by antibodies specific for unmodified antigen). If the term is interpreted as encompassing changes at the physical/chemical level, it is unclear as to what deviations from the normal crystal

structure would or would not be encompassed by the term "the secondary structure and tertiary structure of the pathogenic self-protein is preserved to a large extent". In addition, the phrase "large extent" is not defined in the specification and has no art recognized meaning in the context recited in the claims. Assuming arguendo that it was clear as to what changes were encompassed by preserving the secondary and tertiary structure, it would still be unclear as to what changes did or did not encompass a "large extent". The phrase "large extent" is not defined in the specification and has no art recognized meaning in the context recited in the claims.

Regarding applicants comments about the interpretation of the aforementioned claim limitation in the context of prior art rejections, the MPEP section 2173.06 discloses that interpreting a term for prior art purposes does preclude the rejection of said term under 35 USC 112, second paragraph as indefinite. Regarding the various submitted declarations related to the phrase under consideration, none of said declarations address the newly added limitation that the secondary and tertiary structure is "preserved to a large extent". Assuming arguendo that it was clear as to what changes were encompassed by preserving the secondary and tertiary structure, it would still be unclear as to what changes did or did not encompass a "large extent". The phrase "large extent" is not defined in the specification and has no art recognized meaning in the context recited in the claims. Regarding the first Travers declaration, said declaration addresses the phrase "essentially preserve the overall tertiary structure" wherein said phrase is not currently recited in the claims under consideration. Furthermore, Travers indicates that he would interpret said phrase as meaning:

These 3 passages in my opinion clearly indicate to the skilled reader that "essential preservation of overall tertiary structure" implies that when a peptide containing a T-cell epitope is substituted into a self-protein according to the above-captioned patent application, the substitution is one which introduces a minimum of disturbance in the tertiary structure of the self-protein whereby a maximum number of B-cell epitopes are preserved when comparing to the unmodified self-protein.

In the Delcayre declaration, Delcayre states:

Based on the claim language as amended I understand that the secondary and tertiary structure of a self protein analog is essentially preserved where: (1) the self-protein analog induces an autoantibody response in a subject; and (2) the induced auto antibodies bind to the corresponding unmodified self-protein.

In the Frokjaer declaration, Frokjaer states:

In order to ascertain whether the tertiary structure of the self-protein has been preserved, thereby obtaining optimal therapeutic effects, screening procedures would be necessary. Such screening procedures would be routinely part of a drug development program's search for lead compounds and would be considered early on in the development phase to evaluate which modified self-proteins or self-protein analogs have preserved the tertiary structure of the original protein. Such procedures involve standard experimental techniques for which there are numerous publications. Reference is made to one in particular, which is used as a text book, on protein characterization, e.g. fluorescence spectroscopy, near U.V. circular dichroism, Fourier transformed infrared spectroscopy and multi-dimensional NMR techniques, namely, "Physical Methods to Characterize Pharmaceutical Proteins", Pharmaceutical Biotechnology, vol.7, Eds., J.N. Heron, W. Jisjoot & D.J.A. Crommelin, Plenum Press, New York, (1995). Ideally, for a screening process for lead compounds, two or more of the above techniques would be carried out in order to evaluate whether there is a change in the tertiary structure of the protein.

Thus, applicants **own declarants cannot agree as to what the phrases *"essential preservation of overall tertiary structure" or "essentially preserve the secondary structure and tertiary structure"* mean or *encompass***.

In addition, Frokjaer clearly indicates that said phrase encompasses actual measurement of the secondary and tertiary structure wherein Travers and Delcayre and applicants arguments clearly disagree with this assertion. Thus, it is clear that the limitation under consideration has no art recognized meaning. Regarding applicants comments, the fact that the analog induces an antibody response does not define what changes to the secondary and tertiary structure would or would not be encompassed by the aforementioned term. Furthermore, neither of said declarations address the newly added claim language that the secondary and tertiary structure are preserved to a "large extent". As per above it is unclear as to whether preservation of the secondary and tertiary structure encompasses changes at the physical/chemical level (e.g. crystal structure) or simply functional changes (e.g. still immunogenic antigen as evidenced by antibody binding by antibodies specific for unmodified antigen). If the term is interpreted as encompassing changes at the physical/chemical level, it is unclear as to what deviations from the normal crystal structure would or would not be encompassed by the

term "the secondary structure and tertiary structure of the pathogenic self-protein is essentially preserved". It is unclear as to what changes to the secondary structure or tertiary structure would or would not be encompassed by the aforementioned term. Assuming arguendo that it was clear as to what changes were encompassed by preserving the secondary and tertiary structure, it would still be unclear as to what changes did or did not encompass a "large extent". The phrase "large extent" is not defined in the specification and has no art recognized meaning in the context recited in the claims.

The MPEP section 2173.05(a) [R-3] states:

I. THE MEANING OF EVERY TERM SHOULD BE APPARENT

The meaning of every term used in a claim should be apparent from the prior art or from the specification and drawings at the time the application is filed. Applicants need not confine themselves to the terminology used in the prior art, but are required to make clear and precise the terms that are used to define the invention whereby the metes and bounds of the claimed invention can be ascertained. During patent examination, the pending claims must be given the broadest reasonable interpretation consistent with the specification. In re Morris, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997); In re Prater, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969). See also MPEP § 2111 - § 2111.01.

When the specification states the meaning that a term in the claim is intended to have, the claim is examined using that meaning, in order to achieve a complete exploration of the applicant's invention and its relation to the prior art. In re Zletz, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). The limitation under consideration is only recited in cited passage of the specification, page 3, wherein there is no definition of said term.

Regarding the phrase under consideration, the meaning of said phrase is not apparent from the prior art or the specification. Applicants own declarants cannot even agree as to what said phrase means.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 102 is rejected under 35 U.S.C. 103(a) as being unpatentable over Russell-Jones et al. (WO 92/05192) in view of Dean et al. (US Patent 5,716,596) and Bona et al. (US Patent 5,969,109).

Russell-Jones et al. teach T cell epitopes derived from Trat protein (see Abstract). Russell-Jones et al. teach Trat T cell epitopes are inserted into proteins, wherein the insertion of said peptide increases the antibody response against the protein into which Trat has been inserted (see page 4, lines 24-26 and Abstract). Russell-Jones et al. teach that the Trat peptide is inserted such that the protein still functions as an immunogen. The Trat peptide has been inserted into the immunogen in such a manner as to essentially preserve the overall secondary structure, because the ability of the immunogen to function as an immunogen is maintained (see page 8, first complete paragraph). Whilst the term “secondary and tertiary structure of the self-protein is preserved to a large extent” is indefinite as per above, for the purposes of this rejection it will be assumed the aforementioned limitation encompasses the ability of the immunogen to function as an immunogen is maintained. Russell-Jones et al. teach that the Trat modified immunogen can be used as a vaccine in a composition containing an adjuvant such as saponin (see page 8 and 13). Russell-Jones et al. teach that using recombinant DNA technology that Trat peptide can be inserted into the immunogen via substituting Trat peptide for a peptide contained in said molecule (see page 32 and page 31, first incomplete paragraph). In addition, Bona et al. also teach that a T cell epitope can be substituted into a particular region of a target molecule wherein the T

cell epitope retains immunogenicity (see column 11, second paragraph and column 4). Russell-Jones et al. teach that immunogens used in the aforementioned vaccines can include self proteins such as luteinizing hormone, somatostatin, inhibin, FSH (see page 9 and claim 12). Russell-Jones et al. teach that such vaccines can be used in animals and humans. Somatostatin is a "self protein" in view of its art recognized role in a variety of diseases (see Dean et al., column 2, first paragraph and column 6, third paragraph from bottom). Russell-Jones et al. do not teach use of the particular immunodominant foreign T cell epitopes recited in the claim. Russell-Jones et al. teach that immunodominant foreign T cell epitopes derived from diphtheria toxoid were known in the art (see page 4, first paragraph). Russell-Jones et al. teach that diphtheria toxoid has already been approved for use as a carrier for human vaccines (see page 14, first paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Russell-Jones et al. teach the claimed method except for use of immunodominant foreign T cell epitopes derived from diphtheria toxoid, Bona et al. also teach that a T cell epitope can be substituted into a particular region of a target molecule wherein the T cell epitope retains immunogenicity, Russell-Jones et al. teach that immunodominant foreign T cell epitopes derived from diphtheria toxoid were known in the art and that diphtheria toxoid was already approved as a carrier for human vaccines. One of ordinary skill in the art would have been motivated to do so because immunodominant foreign T cell epitopes derived from diphtheria toxoid were known in the art and diphtheria toxoid was already approved as a carrier for human vaccines.

Regarding applicants comments about antibodies to a self protein, Russell-Jones et al. teach Trat T cell epitopes are inserted into proteins, wherein the insertion of said peptide increases the antibody response against the protein into which Trat has been inserted (see page 4, lines 24-26 and Abstract).

Russell-Jones et al. teach that immunogens used in the aforementioned vaccines can include self proteins such as luteinizing hormone, somatostatin, inhibin, FSH (see page 9 and claim 12). Russell-Jones et al. teach that such vaccines can be used in animals and humans. Somatostatin is a "self protein" in view of its art recognized role in a variety of diseases (see Dean et al., column 2, first paragraph and column 6, third paragraph from bottom). Thus, Russell-Jones et al. clearly teach the use of their invention to elicit antibodies (aka autoantibodies) to a self protein. With regards to reasonable expectation

success, the prior art teaches/renders obvious the claimed invention and is therefore as enabled as the instant application.

Regarding applicants comments and the Legrand declaration, the MPEP section 716.01(b) states:

Nexus Requirement and Evidence of Nonobviousness
TO BE OF PROBATIVE VALUE, ANY SECONDARY EVIDENCE MUST BE RELATED TO THE CLAIMED INVENTION (NEXUS REQUIRED)

The weight attached to evidence of secondary considerations by the examiner will depend upon its relevance to the issue of obviousness and the amount and nature of the evidence. Note the great reliance apparently placed on this type of evidence by the Supreme Court in upholding the patent in United States v. Adams, 383 U.S. 39,148 USPQ 479 (1966). To be given substantial weight in the determination of obviousness or nonobviousness, evidence of secondary considerations must be relevant to the subject matter as claimed, and therefore the examiner must determine whether there is a nexus between the merits of the claimed invention and the evidence of secondary considerations. Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 305 n.42, 227 USPQ 657, 673-674 n. 42 (Fed. Cir. 1985), cert. denied, 475 U.S. 1017 (1986). The term "nexus" designates a factually and legally sufficient connection between the objective evidence of nonobviousness and the claimed invention so that the evidence is of probative value in the determination of nonobviousness. Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 7 USPQ2d 1222 (Fed. Cir.), cert. denied, 488 U.S. 956 (1988).

The Legrand declaration discloses experiments performed using MVA-BN-HER2 which is a modified Vaccinia Ankara based recombinant vaccine vector derived from MVA-BN. The claimed invention is drawn to a method of inducing autoantibodies/treatment that uses a peptide. Thus, the disclosure of experiments performed using MVA-BN-HER2 is not commensurate in scope with the claimed invention which does not use a modified Vaccinia Ankara based recombinant vaccine vector. Furthermore, there is no disclosure in the specification of such vectors or the use of such vectors.

Mandl et al. disclose that the MVA-BN-HER2 vector induces immune responses that are not seen upon vaccination with protein antigen and wherein said responses are critical to the results obtained when said vaccinia vector is administered (see Abstract). Thus, the results obtained in the Legrand declaration clearly depend on use of the MVA-BN-HER2 recombinant vaccinia vaccine vector wherein said vector is not the claimed invention or even an invention disclosed in the specification.

Mandl et al. teach that:

In conclusion, the data presented here demonstrate that a single treatment with MVA-BN-HER2 was able to simultaneously induce Th1-dominated HER-2-specific immune responses and control tumor-induced immunosuppression resulting in potent anti-tumor efficacy. These preclinical results and the excellent safety profile and immunogenicity of MVA-BN even in immune-compromised patients (4–6) provide further support for the development of MVA-BN-HER2 for cancer immunotherapy.

The responses to which Mandl et al. refers depend upon use of the MVA-BN vector, which is not the claimed invention. Furthermore, said vaccinia vector uses a modified tumor antigen wherein the use of tumor antigens is not disclosed in the specification. In addition, the elected species (aka TNFalpha) is not a tumor antigen.

Regarding applicants comments about TraT versus diphtheria toxoid and motivation, Russell-Jones et al. teach that immunodominant foreign T cell epitopes derived from diphtheria toxoid *were known in the art* and that diphtheria toxoid *was already approved as a carrier for human vaccines*. Furthermore the MPEP section 2123 [R-5] states:

> *2123 [R-5] Rejection Over Prior Art's Broad Disclosure Instead of Preferred Embodiments*
>
> *I. PATENTS ARE RELEVANT AS PRIOR ART FOR ALL THEY CONTAIN*
>
> *"The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." In re Heck, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting In re Lemelson, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also > Upsher-Smith Labs. v. Pamlab, LLC, 412 F.3d 1319, 1323, 75 USPQ2d 1213, 1215 (Fed. Cir. 2005)(reference disclosing optional inclusion of a particular component teaches compositions that both do and do not contain that component);< Celeritas Technologies*

Ltd. v. Rockwell International Corp., 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed.").

As per above, the cited reference constitutes art for all it discloses, not just the preferred embodiments. Furthermore, in KSR Int'l Co. v. Teleflex Inc., 550 U.S. m, 2007 WL 1237837, at "13 (2007) it was stated that **"if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill"**. However, in addition, one of ordinary skill in the art would have been motivated to do so because immunodominant foreign T cell epitopes derived from diphtheria toxoid were known in the art and diphtheria toxoid was already approved as a carrier for human vaccines. Regarding applicants comments, Russell-Jones et al. teach Trat T cell epitopes are **inserted** into proteins, wherein the insertion of said peptide increases the antibody response against the protein into which Trat has been inserted (see page 4, lines 24-26, page 31, lines 4-8, claim 14 and Abstract). Russell-Jones et al., page 31 discloses: **"the T cell epitope alone may be inserted within the protein antigen**". Regarding applicants comments about reasonable expectation of success, Russell-Jones et al. teach that using recombinant DNA technology that Trat peptide can be inserted into the immunogen via **substituting** Trat peptide for a peptide contained in said molecule (see page 32 and page 31, first incomplete paragraph). In addition, Bona et al. also teach that a T cell epitope can be **substituted** into a particular region of a target molecule wherein the T cell epitope retains immunogenicity (see column 11, second paragraph and column 4). Russell-Jones et al. teach that the Trat peptide is inserted such that the protein still functions as an immunogen. Regarding applicants comments about "self proteins", Russell-Jones et al. teaches that the claimed invention can be used as a vaccine in humans (see page 33) and can be used to raise antibody responses against such proteins as luteinizing hormone, somatostatin, inhibin, FSH (e.g. ***self proteins***). Russell-Jones et al. teach that, "The at least one "immunogen" which forms part of the complex *is any molecule which it is desirable to use to raise an immune response*.". Regarding applicants comments about somatostatin, there is no evidence of record that

the invention of Russell-Jones et al. lacks enablement regarding this particular embodiment. The prior art is considered enabled in the absence of evidence to the contrary. No such evidence has been provided by applicant. Regarding applicants comments about reasonable expectation of success, Bona et al. also teach that a T cell epitope can be **substituted** into a particular region of a target molecule wherein the T cell epitope retains immunogenicity and have produced such molecules. Regarding applicants comments, Russell-Jones et al. teach that their invention encompasses vaccines for use in animals and humans (see page 33). Russell-Jones et al. teach that one such immunogen could include luteinizing hormone or somatostatin or FSH or inhibin (see page 9). Said proteins could only be of two different origins (human or nonhuman). Thus, based on the disclosure of Russell-Jones et al., one of ordinary skill in the art would at once envisage use of human self-protein as a vaccine as per page 33 of Russell-Jones. Russell-Jones et al. teach Trat T cell epitopes are inserted into proteins, wherein the insertion of said peptide increases the antibody response against the protein into which Trat has been inserted (see page 4, lines 24-26, page 31, lines 4-8, claim 14 and Abstract). Russell-Jones et al. teach that the Trat peptide is inserted such that the protein still functions as an immunogen. Russell-Jones et al. teach that the Trat modified immunogen can be used as a vaccine in a composition containing an adjuvant such as saponin (see page 8 and 13). Russell-Jones et al. teach that using recombinant DNA technology that Trat peptide can be inserted into the immunogen via substituting Trat peptide for a peptide contained in said molecule (see page 31, first incomplete paragraph and claim 14 wherein the nucleic acid of claim 14 is used to recombinantly produce said protein). Russell-Jones et al. teach that immunogens used in the aforementioned vaccines can include self proteins such as luteinizing hormone, somatostatin, inhibin, FSH (see page 9 and claim 12). Russell-Jones et al. teach that such vaccines can be used in animals and humans.

One of ordinary skill in the art would have been motivated to combine the aforementioned teachings because immunodominant foreign T cell epitopes derived from diphtheria toxoid were known in the art and diphtheria toxoid was already approved as a carrier for human vaccines. Furthermore, in the post KSR Int'l Co. v. Teleflex Inc. universe, motivation per se is not even required in a rejection under 35 USC 103. In KSR Int'l Co. v. Teleflex Inc., 550 U.S. m, 2007 WL 1237837, at "13 (2007)

it was stated that **"if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill"**.
Regarding applicants comments about unexpected results, the TraT peptides and Diphtheria toxoid derived peptides taught by Russell-Jones et al. both stimulate T cells from random donors (aka are MHC unrestricted, see Table 3) and would therefore have the functional activities referred to in page 9 of the specification

9. Claim 111 is rejected under 35 U.S.C. 103(a) as being unpatentable over Russell-Jones et al. (WO 92/05192) in view of Dean et al. (US Patent 5,716,596) and Bona et al. (US Patent 5,969,109) as applied to claim 102 above, and further in view of Hellman (WO 93/05810) and Le et al. (US Patent 5,698,195).

The previous rejection renders obvious the claimed invention except for use of TNFα. Hellman teaches that modulation of self proteins responsible for manifestations of a particular disease can be achieved using self-protein conjugated to a carrier which is recognized by T helper cells(see pages 5-12) and wherein the administered hybrid molecule elicits antibodies against said molecule. Le et al. teach that antibodies against TNFα are used to treat TNFα mediated diseases in humans (see abstract and column 5). It would have been prima facies obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because the use of anti TNFα antibodies to treat TNFα mediated disease was known in the art, Hellman teaches that modulation of self proteins responsible for manifestations of a particular disease can be achieved by inducing antibodies against said molecules using self molecules that contain T helper epitopes and Russell-Jones et al. teach methods for inducing antibodies against self proteins using Trat modified molecules.

Applicants arguments are as per addressed above.

10. Claims 103 and 105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Russell-Jones et al. (WO 92/05192) in view of Dean et al. (US Patent 5,716,596) and Bona et al. (US Patent 5,969,109) as applied to claim 102 above, and further in view of Vitiello et al. (US 2003/0099634).

The previous rejection renders obvious the claimed invention except for use of the ovalbumin epitope recited in claim 105. Vitiello et al. disclose a peptide comprising said epitope wherein said epitope is a known immunogenic T cell epitope (see Example 7). It would have been prima facies obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because the previous rejection renders obvious the claimed invention using an immunogenic T cell epitope except for use of the particular peptide recited in the claim whilst Vitiello et al. disclose a peptide comprising said epitope wherein said epitope is a known immunogenic T cell epitope.

Applicants arguments are as per addressed above.

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is (571)272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ron Schwadron/
Primary Examiner, Art Unit 1644

Ron Schwadron, Ph.D.
Primary Examiner, Art Unit 1644